



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,651	07/09/2003	Pu Zhou	1001.1662101	9310
28075	7590	09/21/2005	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			HUSON, MONICA A	
			ART UNIT	PAPER NUMBER
			1732	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

21

Office Action Summary	Application No. 10/615,651	Applicant(s) ZHOU, PU	
	Examiner Monica A. Huson	Art Unit 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-34 is/are pending in the application.
- 4a) Of the above claim(s) 14-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

22

DETAILED ACTION

This office action is in response to the Amendment filed 23 May 2005.

The previous rejections have been withdrawn, as necessitated by applicant's amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Stevens (EP 0841072). Stevens shows that it is known to carry out a method of forming a catheter (Abstract) comprising providing a braid layer having a distal end and a proximal end, an inner lubricious liner positioned within the braid layer (Column 8, lines 1-19); securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer, the first polymer segment having a distal end and a proximal end (Column 8, lines 42-48); cutting through the braid layer and the inner lubricious liner at a cutting position proximate the distal end of the first polymer segment and removing a portion of the braid layer that extends distally of the cutting position (Column 9, lines 3-23); and securing a second polymer segment over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position (Column 10, lines 20-27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5, 7, 9-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens, in view of Wilson (U.S. Patent 5,951,929).

Regarding Claim 2, Stevens teaches the invention of claim 1 as discussed above, but does not expressly teach that the first polymer segment has a melting point that is at least about 10°F above a melting point of the second polymer segment. Wilson teaches using a blend of PEBA and approximately 30% BASO₄ (column 8, lines 32-33), which melts at a range of 385-400°F as the second polymer segment (column 8, lines 60-62) and ANRITEL™ as the first polymer segment, which melts at a temperature of 425°F (column 9, lines 21-36). Thus, Wilson teaches that the first polymer segment has a melting point that is at least 10°F (25°F) above the melting point of the second polymer segment. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's materials during Stevens' method in order that the first polymer segment will not remelt upon application of the second polymer segment (Wilson, column 9, lines 41-50).

Regarding Claim 3, Stevens shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show using shrink tubes. Wilson shows that it is known to carry out a method wherein securing the first polymer segment comprises positioning a heat shrink

Art Unit: 1732

tube over the first polymer segment and applying sufficient heat and pressure to melt the first polymer segment (Column 7, lines 57-67; Column 8, lines 1-5). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's heat shrink tube during Stevens' method in order to most efficiently bond the materials together.

Regarding Claim 4, Stevens shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show using shrink tubes. Wilson shows that it is known to carry out a method wherein securing the second polymer segment comprises positioning a heat shrink tube over the second polymer segment and applying sufficient heat and pressure to melt the second polymer but not enough heat to melt the first polymer segment (Column 8, lines 52-65). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's heat shrink tube during Stevens' method in order to most efficiently bond the materials together.

Regarding Claim 5, Stevens shows the process as claimed as discussed in the rejection of Claims 1 and 4 above, but he does not show specific melting points. Wilson teaches that the first polymer segment has a melting point that is greater than about 400°F and the second polymer segment has a melting point that is less than about 400°F. Wilson teaches using a blend of PEBA and approximately 30% BASO₄ (column 8, lines 32-33), which melts at a range of 385-400°F as the second polymer segment (column 8, lines 60-62) and ANRITEL™ as the first polymer segment, which melts at a temperature of 425°F (column 9, lines 21-36). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Stevens' method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 7, Stevens shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a specific material. Wilson teaches the first polymer segment comprises a polyether-ester elastomer (column 9, lines 20-25). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Stevens' method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 9, Stevens shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a specific material. Wilson teaches the heat shrink tube comprises a perfluoro (ethylene-propylene) copolymer (column 8, lines 50-54). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Stevens' method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 10, Stevens shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a specific material. Wilson teaches the heat shrink tube comprises a perfluoro (ethylene-propylene) copolymer (column 8, lines 50-54). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Stevens' method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 11, Stevens shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show the second polymer segment having different sections. Wilson teaches the second polymer segment comprises in combination a proximal segment configured to overlay the braid layer, an intermediate segment configured to overlay the first

Art Unit: 1732

polymer segment, and a distal segment configured to form a distal tip (column 8, lines 50-65). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific material relationship for Stevens' method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 13, Stevens teaches providing a braid layer that extends sufficiently distally of the cutting position to substantially prevent braid flaring at the cutting position (column 10, lines 32-34, the final cutting includes separating two or more whole catheters which would make the braid layer extend a distance equal to the entire catheter body or more beyond the cutting position), meeting applicant's claim.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens and Wilson, further in view of Zadno-Azizi (US 2004/0015150). Stevens teaches the invention of claim 4 as discussed above, but fails to explicitly teach that the second polymer segment has a melting point that is about 350^oF. Zadno-Azizi teaches a catheter outer coating (PEBAX) that has a melting point at about 350^oF (paragraph 0177). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a material with Zadno-Azizi's specific melting point for Stevens' method in order for the final article to have the specific end-use chemical and physical properties.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens, in view of Ashiya et al (5,947,925). Stevens teaches the invention of claim 1 as discussed above but fails to explicitly teach that the second polymer segment comprises a acetal resin/polyurethane blend.

Art Unit: 1732

Ashiya et al., hereafter "Ashiya," teaches the second polymer segment comprises a acetal resin/polyurethane blend (column 6, lines 40-61, polyoxymethylene is an acetal resin). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Ashiya's specific material for Stevens' method in order for the final article to have the specific end-use chemical and physical properties.

Response to Arguments

Applicant's arguments with respect to claims 1-11 and 13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

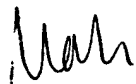
Art Unit: 1732

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A. Huson whose telephone number is 571-272-1198.

The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Colaianni can be reached on 571-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mah
September 14, 2005



MICHAEL P. COLAIANNI
SUPERVISORY PATENT EXAMINER